

REMARKS

Applicants thank Examiner Davis for following up the previous Response and Amendment filed June 20, 2005, with a telephone call and interview prior to acting on the case. After several phone interviews in which agreement was not reached on language that the Examiner believed would render the claims completely clear of any prior art rejections, Applicants nonetheless decided to amend the claims to the present form. Applicants understand from Examiner Davis that such an Amendment would be entered and considered.

The claims are amended to limit the treatment to the use of a composition which "consists of" one of two MEK inhibitor compounds. This is intended to avoid the prior art reference (Shellman *et al.*, hereinafter "Shellman") that, vague as it is, allegedly served as the basis for inherent anticipation of the previous claims (before the Amendment of June 20, 2005). The term "comprising" remains and relates to the "contacting" (claim 1) or "administering" (claims 9 and 16) - where it is intended to permit a method that may other involve steps or actions, while the only MEK inhibitors that may be used in the method are the two recited compounds.

Applicants understand from the interview that the Office's position would be that these claims would nevertheless permit the use of combinations of drugs that the Shellman reference discloses, resulting in a rejection under § 103.

What does Shellman teach?

The MEK inhibitor U0126, which has a similar biochemical mode of action to the two compounds in the claims, participates in inducing apoptosis in melanoma cells. However, it is impossible to tell from the reference whether it does so alone or only in combination with Cisplatin.

The Amended Claims

According to the amended claims, one contacts melanoma cells with either of two compounds: PD98059 or PD184352. Because of the term "comprising contacting" or "comprising administering" the Office appears to take the position that the claim would include in its scope, in addition to the use of the composition limited to one of two compounds, the performance of any other act or step, including contacting the cells or treating the subject with, for example, with another MEK inhibitor, specifically:

- (a) U0126 (disclosed in Shellman.) which, in view of Applicant's specification is known to *inherently kill* melanoma cells; or.

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- (b) U0126 in combination with other drugs - such as the combination with Cisplatin disclosed by Shellman

It is Applicants' view that nothing in the prior art teaches or suggests that one combine in a single anti-melanoma treatment approach, two different MEK inhibitors of the class to which PD98059 and PD184352 belong (noncompetitive; do not inhibit binding of MEK to ATP). Applicants understand from Examiner Davis that the possibility of such a combination being within the scope of the amended claims would be the basis for a new § 103 rejection. However, Applicants believe that a method of killing melanoma cells (claim 1) or treating melanoma (claim 9 or 16) by using, for example any of the following combinations (related to the Shellman disclosure)

- (a) PD98059 + U0126 (or any other MEK inhibitor);
- (b) PD98059 + U0126 + Cisplatin;
- (c) PD98059 + U0126 + X (where X is any compound);
- (d) PD184352 + U0126 (or any other MEK inhibitor);
- (e) PD184352 + U0126 + Cisplatin; or
- (f) PD184352 + U0126 + X

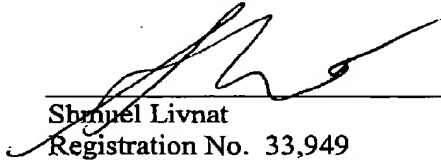
would not be obvious over Shellman *et al.* or any other art of record

CONCLUSION

In conclusion, it is respectfully requested that the above amendments, remarks and requests be considered and entered. Applicant respectfully submits that all the present claims are in condition for allowance, and respectfully requests early notice of such favorable action.

Respectfully submitted,

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